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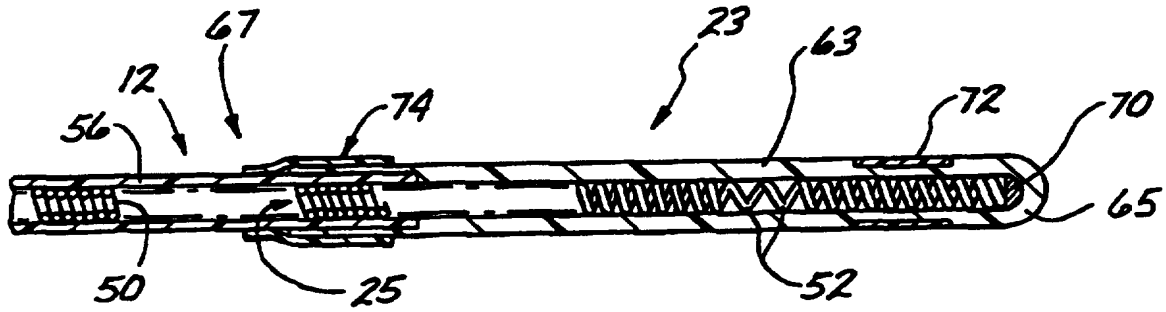

(57) Abstract

A catheter (10) having walls defining a lumen extending between a proximal end (16) and a distal end (18). First portions (41) of the tube disposed at the distal end (18) include first wall portions providing the lumen with a first inside diameter less than about 3F. Second portions (45) of the tube disposed proximally of the first portions (41) include a second wall portion with an inside diameter greater than the first inside diameter. A balloon (23) disposed at the distal end (18) of the tube along the first portions (41) of the tube is inflatable by introducing a liquid into the lumen (25) and deflated by removing the liquid from the lumen (25). The first wall portions with an inside diameter less than bout 0.010 inches have a tendency to form an air lock during deflation of the balloon. The first portions (41) of the tube having a first length sufficiently short to inhibit formation air lock during deflation of the balloon.

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EMBOLECTOMY CATHETER AND METHOD FOR MAKING SAME

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to surgical devices such as catheters for less invasively accessing remote regions of a body conduit, and relates more specifically to embolectomy catheters for removing emboli and thrombi from blood vessels.

Discussion of the Prior Art

Emboli consist of blood clots including calculi and other minerals which form deposits in blood vessels. Emboli are free floating within the vessel but nevertheless restrict blood flow. Their free-floating characteristics are of greatest concern as they have a tendency to migrate into smaller regions where they can lodge to fully occlude a vessel.

Thrombi are best described as emboli which have attached themselves to the walls of the vessel. Since they are not free floating, but rather stationary, the thrombi restrict blood flow to an even greater extent than emboli. Although thrombi do not migrate, they can come loose from the wall again forming free floating emboli. Consequently, thrombi can be just as dangerous as emboli.

In an effort to remove these dangerous deposits from a blood vessel, the prior art has relied on balloon catheters to access the deposits. The catheter is inserted through an incision in the vessel wall and the balloon is directed in a deflated state past the emboli. Then the balloon is inflated and the entire catheter is removed back through the incision. As the catheter is withdrawn, the inflated balloon pushes the emboli and thrombi along the vessel and out the incision.

Although the emboli are generally thought to be more dangerous than the thrombi, this embolectomy procedure is of greatest concern with respect to the thrombi. Since larger forces are required to dislodge the thrombi from the vessel wall, the balloons tend to be more vulnerable to this type of deposit. If the balloon ruptures, the inflation media of the balloon is immediately discharged into the blood stream. For this reason a liquid such as water or saline, is generally preferred as an inflation media for the balloon.

This invention is concerned with the smaller embolectomy catheters which are required to traverse small vessels in the foot, hand, and arm of the body. These catheters may be as long as eighty centimeters with an outside diameter such as 2 French (2F). With such a small outside diameter, the inflation lumen is commonly restricted to only 0.010 inches.

While the small diameters of these catheters are required to reach into small vessels, the minute size of the inflation lumen has presented problems when one attempts to deflate the balloon. Such deflation is required because the catheter is typically reinserted several times in order to fully clear the deposits from the

blood vessel. Each time the catheter is reinserted, the balloon must be deflated to achieve the low profile needed for further insertion of the catheter.

Springs are commonly included in embolectomy catheters in order to add torqueability and flexibility to the overall construction, and to add directability to the distal end of the catheter. However, the thickness added to the catheter wall by a spring detracts significantly from the overall requirements of a small outside diameter and a large inside diameter.

When the catheter is manufactured and packaged, air is present in the inflation lumen. When the surgeon attempts to inflate the balloon using water or saline, small pockets of this air tend to form bubbles along the interior surface of the inflation lumen. These bubbles can cause "airlock" when one attempts to deflate the balloon. Airlock occurs when forces which would tend to expel the non-compressible liquid inflation media, act only to compress the gas or air of the bubbles. When this occurs, the inflation media can not be expelled; consequently, the balloon remains inflated.

In larger catheters, the elastic force of the balloon is usually sufficient to expel the inflation media. In order to facilitate this expulsion in the very small embolectomy catheters, attempts have been made to pull a vacuum on the inflation lumen in order to withdraw the inflation liquid. These attempts have generally been unsuccessful. Even compressing the balloon can be futile in relieving the airlock in a small inflation lumen. The surgeon's choice at this point is usually to discard the airlocked catheter and use a new catheter for the next passage.

Attempts have also been made to insure that all of the air in the inflation lumen has been expelled prior to inflation with the liquid. A vacuum can be pulled on the inflation lumen and the shaft of the catheter repeatedly tapped in an effort to dislodge any air bubbles. Failure to fully evacuate the catheter of air bubbles, leaves the surgeon with a potential airlock. Even using this procedure, he must begin the surgery without knowing whether the balloon will ultimately deflate. Of course, this cumbersome and questionable procedure for expelling the air, must be repeated for each new catheter.

Further attempts have been made to use a gas for the inflation medium. Although this may be a solution to the airlock problem, it raises other concerns with respect to gas in the blood stream in the event of a balloon rupture. In order to decrease the severity of this consequence, gases such as carbon dioxide, which are more capable of being absorbed into the blood, have been recommended.

In spite of all of these attempts to address the airlock problem, there has remained a need for a very small embolectomy catheter which can be inflated with a liquid and readily deflated to permit repeated passes with the catheter.

SUMMARY OF THE INVENTION

These deficiencies of the prior art have been overcome with several apparatus and procedures associated with the present invention. Initially it was appreciated that the airlock problem derives from the tendency of the air bubbles to form on the inner surface of the walls which define the extremely small inflation lumen.

In one embodiment of the present invention, the inside diameter of the inflation lumen is increased without increasing the outside diameter which is critical to the small size of the catheter. In this embodiment the spring is removed from the catheter body except at the distal end where its flexibility aids in tracking the vessel.

In accordance with another solution, it was found that the size of the inside diameter could be increased without increasing the outside diameter, by forming the spring from a wire having a rectangular cross section. This tended to reduce the diameter occupied by the spring so that the size of the inflation lumen could be increased.

It was also found that the tenacious attachment of the air bubbles to the catheter wall is dependent upon the surface energy of the walls. When these walls were coated with a surfactant, this surface energy was reduced along with the probability of an airlock.

Perhaps the greatest effect was achieved when it was discovered that the ability to withdraw a liquid inflation medium through a small diameter lumen was dependent on the length of that lumen. Whereas the small embolectomy catheters of the prior art have provided this small lumen throughout their entire length, such as 80 centimeters, it was found that a reduction in this length could totally avoid the airlock problem. Thus in accordance with one aspect of this invention, the small 2F diameter is maintained only at the distal end of the catheter where that dimension is critical. This small distal portion is limited in length so that the small inflation lumen is also limited in length. The remainder of the catheter can be formed with a larger inside diameter which does not contribute to the airlock problem.

The end result is that the surgeon can now confidently begin this embolectomy surgery with a single catheter. Furthermore, the catheter need not be specially purged of air prior to inflation. Now the small 2F catheters can be relied on to function in the same manner as the larger embolectomy catheters, free of any problems associated with airlock.

These and other features and advantages of the invention will become more apparent with a discussion of preferred embodiments of the apparatus and method, and reference to the associated drawing.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is an axial cross-section view of a blood vessel and a catheter of the present invention being inserted and withdrawn to remove thrombi and emboli from the vessel;

Fig. 2 is a side view of one embodiment of the catheter of the present invention showing various regions along the axis of the catheter;

Fig. 3 is an enlarged view of a transition region associated with the catheter of Fig. 2;

Fig. 4 is an enlarged cross sectional view of a balloon region associated with the catheter of Fig. 2;

Fig. 5 - Fig. 10 are illustrations of the various steps which can be employed in a preferred method for manufacturing the catheter of the present invention;

Fig. 5 is a side view of a tapered mandrel;

Fig. 6 is a side view illustrating a step of winding a tapered spring on the mandrel;

Fig. 7 is a side view illustrating a step of stretching the spring in the balloon region of the catheter;

Fig. 8 is a side view illustrating the coextrusion of a jacket onto the tapered spring;

Fig. 9 is a side view illustrating a the step of limiting the length of the distal portion of the catheter; and

Fig. 10 is a side view illustrating a step of attaching the
balloon to the distal end of the catheter.

DESCRIPTION OF PREFERRED EMBODIMENTS AND BEST MODE OF THE INVENTION

An embolectomy catheter is illustrated in Figure 1 and designated generally by the reference numeral 10. The catheter 10 includes an elongate tube 12 which extends along an axis 14 between a proximal end 16 and a distal end 18. A hub 21 is positioned at the proximal end 16 and an inflatable balloon 23 is disposed at the distal end 18. The balloon 23, which may be either distensible or non-distensible, is inflatable through an inflation lumen 25 which extends along the length of the catheter 10 through the hub 21 and the tube 12.

The embolectomy catheter 10 is used for removing deposits from a blood vessel. Such a vessel is designated by the reference numeral 27 in Figure 1, where the deposits are in the form of an embolus 30 or thrombus 32. The vessel 27 includes a vessel wall 34 which defines a vessel conduit or passage 35 within which the blood flows.

Initially, an incision 36 is formed in the vessel wall 34. The distal end 18 of the catheter 10 is then inserted through the incision 36, into the vessel passage 35, and past the emboli 30 or thrombi 32. At this location, the balloon 23 is inflated, typically by introducing a liquid such as saline or water into the inflation lumen 25 of the tube 12. After the balloon 23 has been inflated to fully occupy the passage 35, the catheter 10 is withdrawn proximally as the balloon 23 pushes the embolus 30 and the thrombus 32 proximally and outwardly through the incision 36. The vessel 27 is commonly pinched or otherwise occluded beyond the incision 36 as shown by the reference numeral 38.

Thus the balloon 23 has a contracted state, illustrated by the solid lines in Figure 1, and an inflated state illustrated by the dotted lines in Figure 1. In the contracted state, the balloon 23 has a low profile which permits the catheter 10 to be pushed through the vessel passage 35. In the inflated state, the balloon 23 is radially enlarged to fully occupy the passage 35. It is not uncommon that several passes of the catheter 10 are required in order to remove all of the emboli and thrombi from the vessel passage 35. In such an event, the balloon 23 must be deflated before it can be reinserted into the vessel 27. It is the deflation of the balloon 23 between repeated passes of the catheter 10 that has developed the problem previously referred to as an "airlock."

The airlock problem is solved in accordance with the present invention where the tube 12 is provided with three separate sections: a distal section 41, a transition section 43, and a proximal section 45. The distal section 41 is the operative portion of the catheter 10. It is this section 41 which must pass into the narrowest regions of the vessel 27 and carry the balloon 23 beyond the embolus 30 or thrombus 32. With these requirements, it is important that the distal section 41 be formed so that the tube 12 in this section 41 has the smallest outside diameter. For the smallest embolectomy catheters, which suffer the most from the airlock problem, the outside diameter of the tube 12 in this distal section 41 will typically be less than 3F. In a preferred embodiment, this outside diameter is only 2F.

In the proximal section 45, the tube 12 can have a larger outside diameter than in the distal section 41. In fact, a sleeve 47 can be provided in this section 45 for strain relief. Between the distal section 41 and the proximal section 45, the transition section 43 will include a taper 54 which transitions the size of the tube 12 between the outside diameter of the distal section 41 and the outside diameter of the proximal section 45.

Focusing on this transition section 43, one can see the construction of a preferred embodiment in the enlarged view of Figure 3. In this case, a spring 50 is wound from a very thin wire having a cross sectional diameter as small .005 inches. This spring 50 is tightly wound with convolutions 52 which are closely spaced except in the region of the balloon 23. The spring 50 is tapered in the transition region 43 so that it has an outside diameter of about .031 inches in the proximal region 45 and an outside diameter of about .020 inches in the distal region 41.

These dimensions provide the spring 50 with inside diameters of .021 inches and .010 inches in the respective sections 45 and 41. It is these inside diameters of the spring 50 in a preferred embodiment which define the inflation lumen 25 of the catheter 10. The length of the taper in the transition region 43 is in a range between 1 inches and 4 inch with a preferred length of about 3 inches in the best mode of the invention.

It is preferable that the spring 50 extend throughout the length of the catheter 10 so that the distal end 18 is not susceptible to separation from the remainder of the catheter 10. This structural integrity of the catheter 10 is further enhanced by the formation of a coating or jacket 56 over the spring 50. In a preferred method of manufacture, the jacket 56 is formed by coextrusion wherein the jacket 56 is applied onto the outer surface of the spring 50 with a generally constant cross-sectional area. Where the spring 50 has a smaller outside diameter, for example in the distal section 41, the jacket 56 may have a thickness of about .005 inches. In the larger proximal section 45, the jacket 56 may have a thickness of about .004 inches.

A balloon region 61 is included in the distal section 41 as best illustrated in Figure 4. From this view it is apparent that the distal end of the spring 50 extends beyond the distal end of the jacket 56 in a preferred embodiment. In this region 61 where the spring 50 is exposed, the convolutions 52 are preferably spread to form spaced convolutions 58 which facilitate fluid communication with the inflation lumen 25 of the catheter 10.

The balloon 23 is formed as a latex sleeve 63 having a closed end 65, and an opposing end 67 which is open to

receive the distal end of the tube 12. In this embodiment, the non-jacketed end of the spring 50 as well of the distal end of the jacket 12 are disposed within the sleeve 63. A plug 70 of UV adhesive can be disposed between the spring 50 and the closed end 65 of the sleeve 63.

With this construction, the sleeve 30 is attached to the spring 50 by a winding 72 which is preferably located distally of the spaced convolutions 58. A proximal winding 74 can be formed over the open end 67 of the sleeve 63 so that it engages both the sleeve 63 and the jacket 56. The winding 74 is preferably located proximally of the spaced convolutions 58.

The balloon 23 is illustrated in its contracted state in Figure 4. In order to inflate the balloon, the liquid inflation media, such as water or saline, is introduced under pressure through the inflation lumen 25 and the spaced convolutions 58, thereby forcing the sleeve 63 to expand radially outwardly between the windings 72 and 74.

It is of particular interest to the present invention that the distal section 41 has the reduced outside diameter which is characteristic of these very small embolectomy catheters. The length of this narrow distal section 41 must be maintained over a distance sufficient to reach into the small blood vessels associated with the foot, hand, and arm of a patient. It has been found that this length need not be the entire length of the catheter 10, as is the case with the prior art, but that a distance ranging between 10 and 15 centimeters will provide the necessary degree of access. Beyond that length, the size of the catheter 10 need not be restricted to such a small outside diameter.

With the discovery that the airlock problem is associated with the length of the very small inside diameter of the tube 12, the length of the distal section 41 can be limited without sacrificing the small size requirements of the procedure. By relaxing the requirement for length in the smallest section of the catheter, a synergy develops so that the airlock problem commonly associated with these small catheters is totally avoided. It has been found that if the distal section 41, having an inside diameter of only .010 inches, is provided with a length not greater than 25 centimeters, then the airlock problem does not occur even in the absence of initial purging. This enables the surgeon to begin his embolectomy procedure confident that a single catheter 10 can be used repeatedly to fully address the removal of the embolus 30 or thrombus 32 from the vessel 27.

A preferred method for manufacturing the catheter 10 is illustrated in Figures 5 - 11. Initially a mandrel 81 can be provided as shown in Figure 5. The mandrel 81 preferably has a length equivalent to that desired for the spring 50 and an outside surface 83 with a diameter and other shape characteristics desired for the inside of the spring 50. Since this outside surface 83 of the mandrel 81 controls the shape and size of the inflation lumen 25, this step for providing the mandrel 81 is of particular importance to the invention. In a preferred embodiment, a distal end 85 of the mandrel 81 is provided with a diameter such as .010 inches, while a proximal end 87 is provided with a diameter such as .021 inches. Between these two ends 85 and 87, the outer surface 83 includes a taper 90 formed in accordance with the shape desired for the transition section 43.

In accordance with Figure 6, the spring 50 is wound on the mandrel 81 forming the closely spaced convolutions 52 along the length of the mandrel 81. The spring in a preferred embodiment is wound from a stainless steel wire 92 having a circular cross section and a diameter of .005 inches. In another embodiment, the wire 92 may have a cross section in the shape of a rectangle with 94 a radial dimension such as .0045. In such an embodiment, the spring 50 has a radial wall thickness of only about .0045 inches. This enables the distal section 41 to maintain the 2F outside diameter with an enlarged inside diameter such as .011 inches.

After the spring 50 has been formed, the mandrel 81 can be removed. Then, as illustrated in Figure 7, the convolutions 52 in the balloon section 61 can be stretched to form the spaced convolutions 58.

In the next step of the process, illustrated in Figure 8, the jacket 56 is coextruded onto the outer surface of the spring 50. The spring 50 is introduced preferably at a constant rate through an extrusion die 96. The material of the jacket 56, is preferrably a thermoplastic elastomer such as Hytrel, a registered trademark of E. I. DuPont de Nemours. In accordance with the preferred process, the material is heated and forced through the die 96 to form the jacket 56 around the spring 50. If the material of the jacket 50 is extruded at a constant volume and the spring 50 is moved a constant linear velocity, the thickness of the jacket 56 will be thinner (such as .003 inches) in the proximal section 45, and thicker (such as .004 inches) in the smaller distal section 41.

An important step in this process calls for a reduction in the length of the distal section 41 for the

important reasons previously discussed. This step, illustrated in Figure 9, calls for the limiting of the length of the distal section 41 to a range of about 10 to 25 centimeters. This step is accomplished in a preferred embodiment by cutting the tube 12 of the distal section 41 with a pair of wire cutters 97. The manner in which this length is limited may not be important in a particular method of the invention; however, the derivation of the appropriate length in accordance with the present invention can be of critical importance.

After the tube 12 has been cut, or otherwise limited in the distal section 41, a coating can be applied to the inner surface of the tube 12 which defines the inflation lumen 25. This coating can be applied by dipping the distal section 41 into a coating material 98, as illustrated in Figure 10, and then draining the material from the lumen 25 as the coating is permitted to dry. In a preferred method the coating material 98 can be any surfactant such as ethylene glycol. This compound functions as a surfactant and accordingly decreases the surface energy of the tube 12. As a result, air bubbles which might contribute to an airlock are more limited in volume and number.

In the final steps of a preferred manufacturing process, the adhesive 70 is applied and the sleeve 63 is positioned over the distal end of the tube 12. Then using a tread 100 formed from a polyester material, the windings 72 and 74 can be formed to bond the sleeve 63 to the spring 50 and jacket 56. This winding step forms the balloon 23 over the spaced convolutions 58.

In accordance with these manufacturing steps, a preferred embodiment of the catheter 10 is formed with the

distal section 41 having a diameter less than about 3F. The length of this distal section 41 is sufficiently long to provide access to even remote deposits such as the embolus 32. However, the distal section 41 is sufficiently short to avoid any problems associated with airlock. The possibility of an airlock problem can be even further reduced by increasing the size of the inflation lumen 25 in this distal section 41 and by coating the inside surface of the spring 50 with a surfactant as previously disclosed.

Although the foregoing embodiments represent the best mode of the concept, it will be apparent that many variations on this apparatus and method will capture the advantages and synergies of the invention. In general, the concept is applicable whenever a tube is used to equalize the pressure between two regions. This may include regions such as body cavities in addition to the region formed by an inflated balloon. The materials associated with a particular structure may also vary considerable. Notably, any materials providing a reduced surface energy would capture the advantage associated with the coating 98 in the described embodiment. Alterations in the length in the various sections 41 and 43 may also be possible in order to achieve a reduced propensity for airlock. It will also be readily apparent that the balloon 23 can be formed in accordance with many of the constructions already found in the prior art. Furthermore, the spring 50 can be wound from a wire having generally any configuration. In general, any cross-sectional shape for the wire which provides a reduced radial dimension can increase the inside diameter of the lumen 25 without increasing the outside diameter of the catheter 10.

Given these wide variations, which are all within the scope of this concept, one is cautioned not to restrict the

invention to the embodiments which have been specifically disclosed and illustrated, but rather encouraged to determine the scope of the invention only with reference to the following claims.

CLAIMS

1. A catheter, comprising:

an elongate tube having walls extending between a proximal end and a distal end, the walls defining a lumen of the tube;

first portions of the tube disposed at the distal end of the tube and including first wall portions providing the lumen with a first inside diameter less than about 3F;

second portions of the tube disposed proximally of the first portions of the tube and including a second wall portion with an inside diameter greater than the first inside diameter;

a balloon disposed at the distal end of the tube along the first portions of the tube, the balloon being inflatable through the lumen of the tube between a contracted state and an inflated state;

means for introducing a liquid into the lumen of the tube to inflate the balloon;

means for removing the liquid from the lumen to deflate the balloon;

the first wall portions having a tendency to develop an air lock when of the balloon is being deflated; and

the first wall portions of the tube having a length sufficiently short to inhibit the air lock during deflation of the balloon.

2. The catheter recited in Claim 1 wherein the first length of the first wall portions is in a range not greater than about 25 centimeters.

3. The catheter recited in Claim 2 wherein the first length is less than about 15 inches.

4. The catheter recited in Claim 1 further comprising a coating disposed on the first walls defining the lumen, the coating including a surfactant having properties for reducing the surface energy of the first walls.

5. The catheter recited in Claim 1 wherein the first wall includes:

a spring defining the first lumen; and

a jacket disposed over the spring.

6. The catheter recited in Claim 5 wherein the spring is formed from a wire having in radial cross-section the general configuration of a rectangle.

7. A method for making a catheter, comprising the steps of:

providing a tube having an elongate configuration and a lumen extending between a proximal end and a distal end, the tube having a first portion at the distal end with a first diameter and a second portion at the proximal end with a second diameter larger than the first diameter, and a transition portion disposed between the first portion of the tube and the second portion of the tube;

fixing a balloon along the first portion of the tube, the balloon being inflatable to expand the balloon from a contracted state to an inflated state, and being deflatable to contract the balloon from the inflated state to the contracted state;

limiting the outside diameter of the first portion of the tube to a range less than about 3F, the first inside diameter of the first portions being sufficiently small

that the first portions of the tube have a tendency to develop an air lock when the balloon is deflated; and

limiting the length of the first portions of the tube to less than about 25 centimeters in order to prevent the air lock from developing in the first portions of the tube during deflation of the balloon.

8. The method recited in Claim 7 further comprising the step of coating the lumen of the first portions of the tube with a surfactant in order to reduce the energy associated with the surface defining the lumen.

9. The method recited in Claim 7 wherein the first providing step comprises the step of:

forming an elongate spring with a length sufficient to extend between the proximal end and the distal end of the tube, the spring defining the inside diameter of the tube; and

forming a jacket over the spring, the jacket defining the outside diameter of the tube.

10. The method recited in Claim 9 wherein the step of forming the spring includes the step of winding the spring from a wire having in radial cross-sectional the shape of a rectangle.

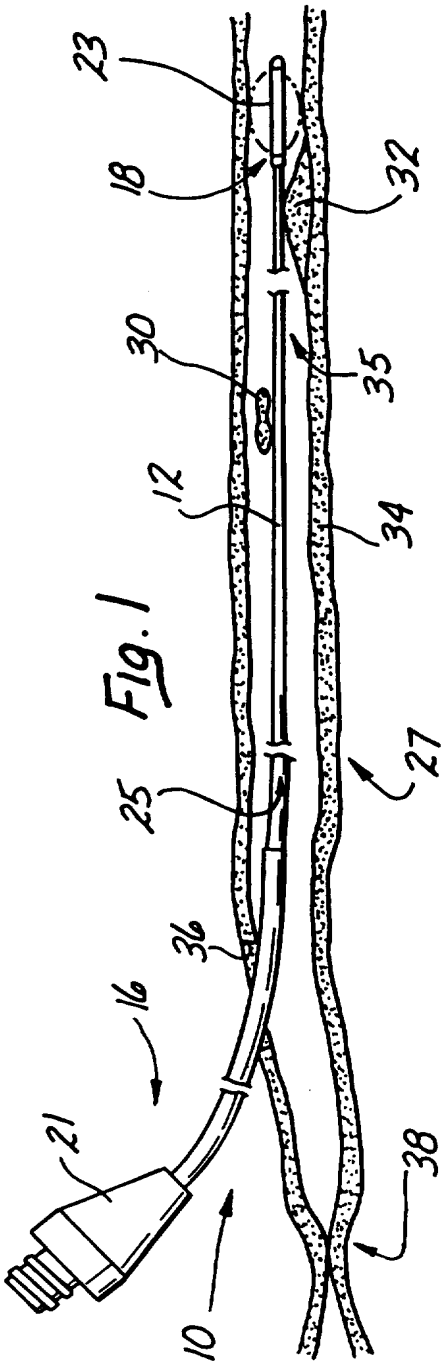

Fig. 1

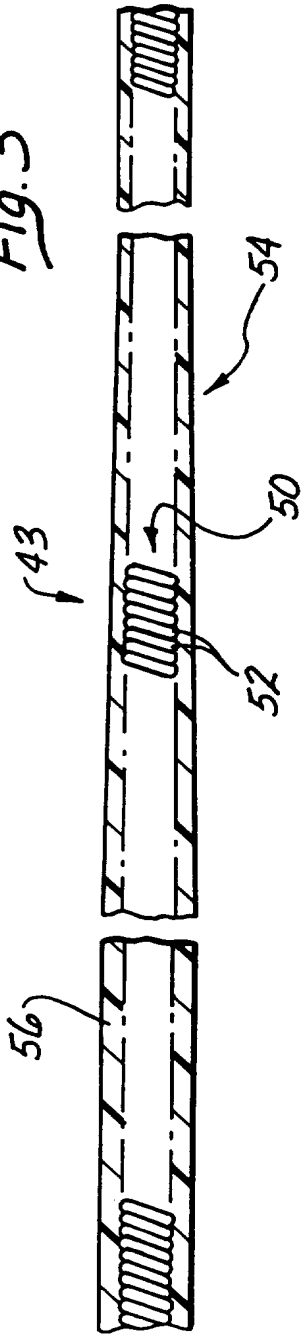

Fig. 3

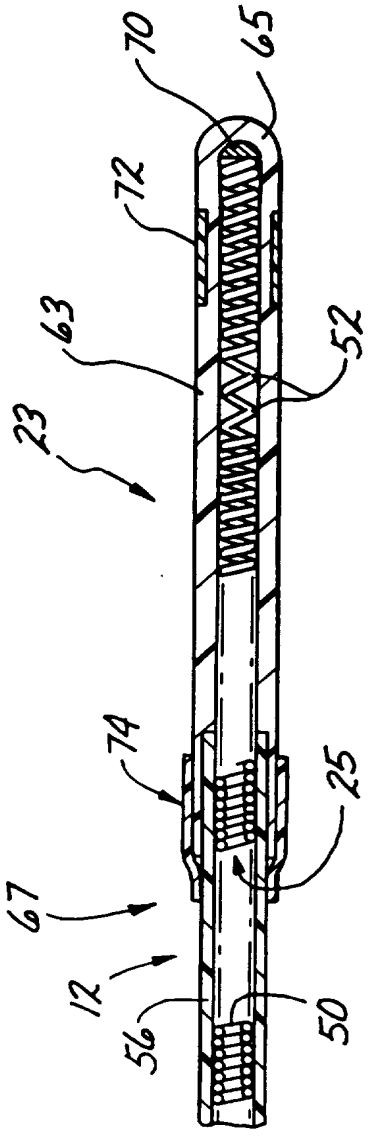

Fig. 4

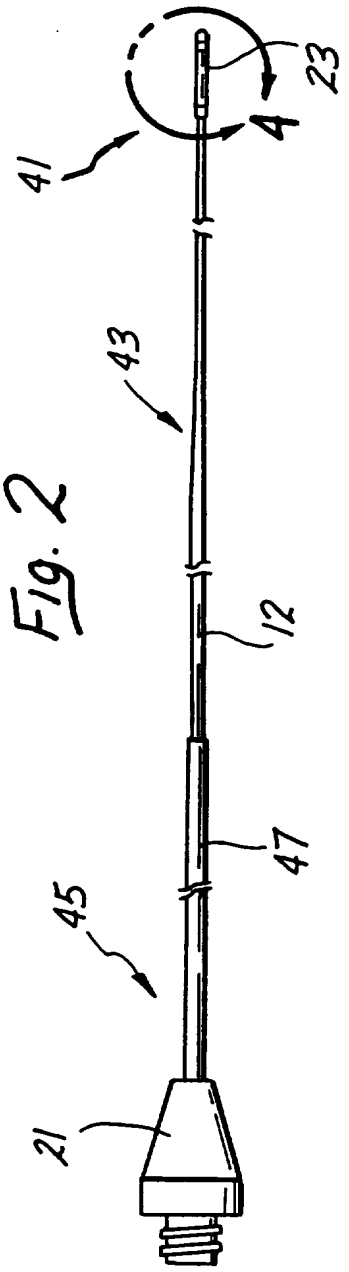

Fig. 2

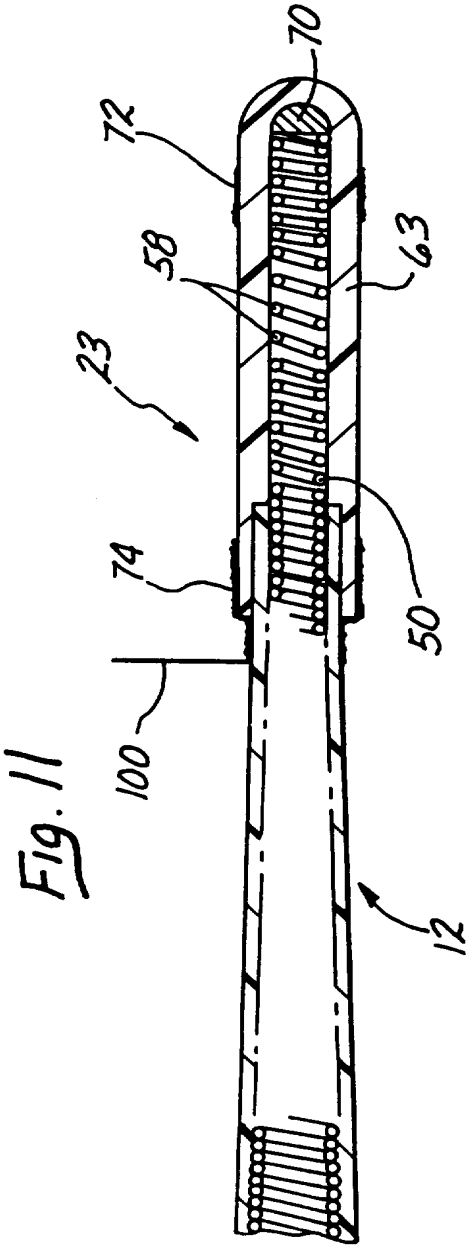

Fig. 11

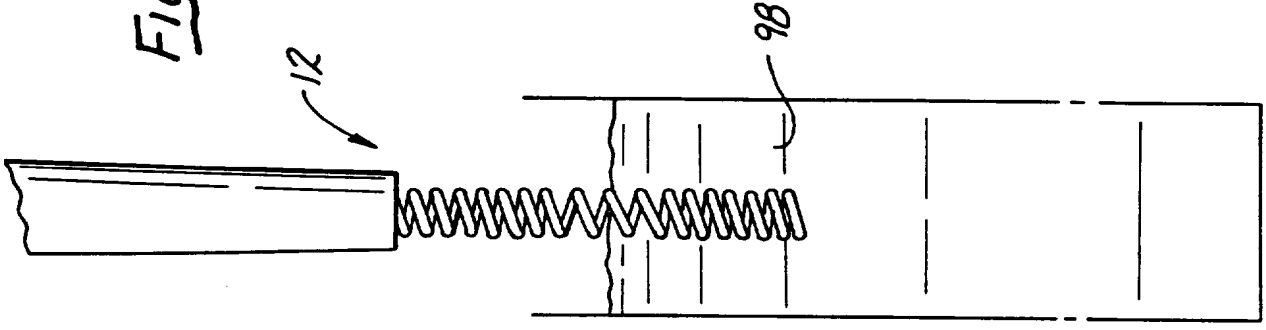

Fig. 10

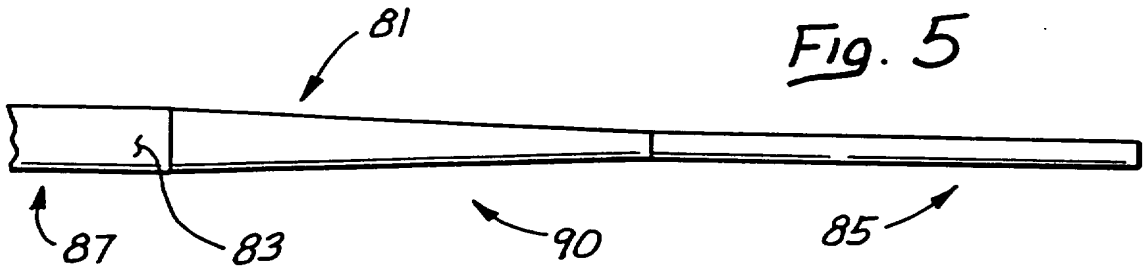

Fig. 5

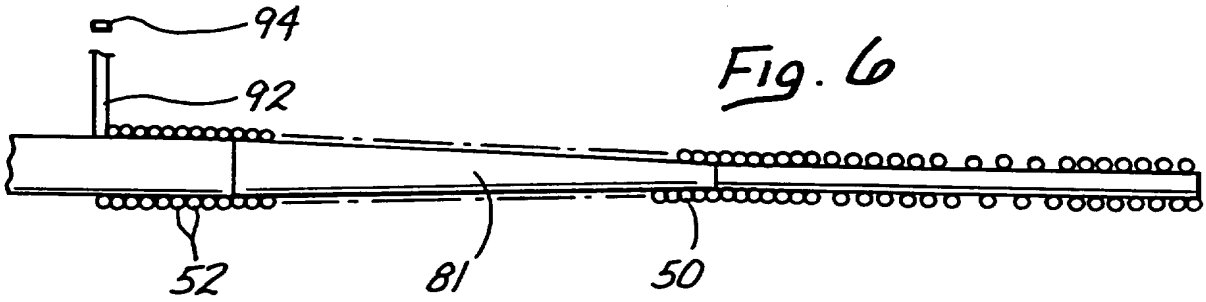

Fig. 6

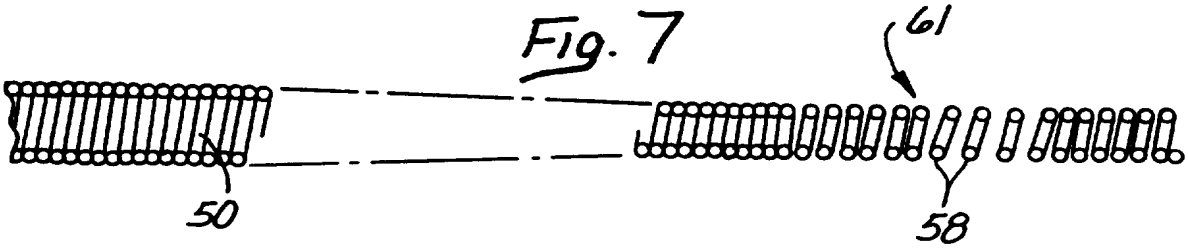

Fig. 7

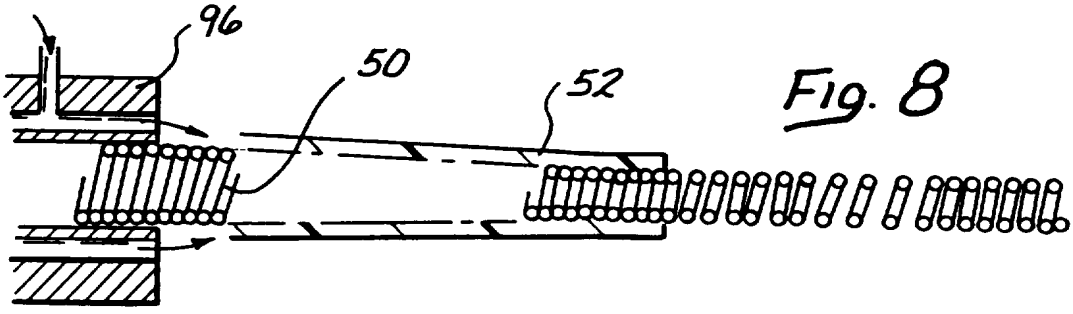

Fig. 8

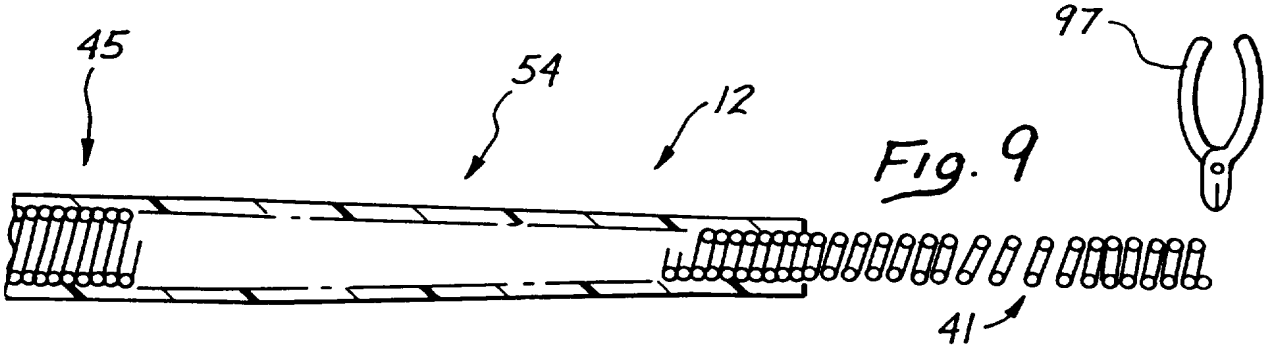

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/12021

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00
US CL :604/280

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96, 264, 280, 282; 606/192, 194, 200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,176,661 (EVARD ET AL.) 05 January 1993, note Fig. 5, and the table of column 6.	1, 4-6 --- 2, 3, 7, 9, 10
X, P	US, A, 5,423,754 (CORNELIUS ET AL.) 13 June 1995, note column 5 line 50 through column 6 line 10, column 6 lines 19-23, and column 7 lines 37-51.	1-4, 7, 8
A	US, A, 5,171,221 (SAMSON) 15 December 1992, note Abstract.	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
01 NOVEMBER 1995	05 DEC 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CORRINE MCDERMOTT Telephone No. (703) 308-2111

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